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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,167	06/08/2000	Brendan Larder	07691.0006	9773

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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 07/29/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/589,167

Applicant(s)

LARDER ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

Applicants' arguments, filed 29 March 2002, have been fully considered by they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-7, 13-20 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 and 13-19 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP 2172.01. The omitted steps are: the actual steps required to "predict resistance" that must be performed to train the neural network by the trained neural net. Without such steps explicitly recited, the "predicting" step is entirely unclear as to how such predicting is to be performed. Further, the method is lacking steps wherein a sample is obtained, and the genetic information of the pathogen is obtained from the sample. Without such steps, the method is not being performed on any real data, and is simply another training exercise using data already available in the database.

Applicant asserts that by way of amendment to the claims, the above rejection is overcome. However, the amendments do not reflect the actual steps necessary to train the neural

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network. Does this training involve extracting local motif patterns typical of a relevant mutation? Does the training involve computing a probability in order to compare data? Without such steps outlined, it is unclear as to how to interpret the steps of said invention.

In claims 1, 13 and 20, ~~it is unclear~~ it is unclear what exactly constitutes a trained neural network. Does it comprise the algorithms and the training set? Or just the algorithms that result from modifications through training? How much training must occur? How much data should be used? Again, it would appear that specific data and events, as well as specific algorithms and instructions, are required for such training.

### ***Claims Rejections-35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7 and 13-22 remain rejected under 35 U.S.C. 102(a) as being anticipated by Draghici et al. (*Correlation of HIV Protease Structure with Indinavir Resistance: A Data Mining Resistance: a Data Mining and Neural Networks Approach*. Proceedings of SPIE, vol. 4057, April 2000, pages 319-329 in: *Data Mining and Knowledge Discovery: Theory, Tools, and Technology II*). Draghici, as stated in the previous office action, discloses methods of predicting the resistance of a pathogen (HIV) to a therapeutic agent (Indinavir) using a feed forward neural network (page 324). The genetic sequence of the protease gene of HIV-1 was used to model the protein structure, along with data regarding known mutations, and their associated resistance or

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sensitivity to Indinavir. The feed forward network comprised at least an input node, at least one hidden layer, and an output node. Therefore, the disclosure of Draghici et al. meets the limitations of the rejected claims.

Applicants argues that Draghici et al. do not teach a neural network that is trained using a training data set comprising members that correspond to at least one genetic mutation that correlates to a phenotypic change that causes a change in resistance of the pathogen to the therapeutic agent and using this trained neural network to identify at least one mutation of the determined genetic sequence that confers resistance to the therapeutic agent.

However, this is not persuasive because Draghici et al. clearly teach the construction of data from mutations and the known genotype of the wildtype (page 323). Furthermore, a training set is constructed that had patterns with fixed numbers of units so that a master list of mutants is compiled. They constructed a pattern set with mutants in order to extract common features that could be related to resistance (page 325, paragraph 1). These patterns sets were then divided into training sets and their resistance to Indinavir was predicted. This method is clearly based upon the premise of locating common mutations that are present in many mutants that help define a motif that confers resistance of the pathogen to the therapeutic agent (Indinavir).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims are rejected.

### *Inquiries*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

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July 25, 2002

Lori A. Clow, Ph.D.

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*Lori A. Clow*



MICHAEL P. WOODWARD  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600